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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

LIFESCAN, INC. and LIFESCAN SCOTLAND, LTD,

Plaintiffs,

v.

SHASTA TECHNOLOGIES, LLC, INSTACARE CORP., PHARMATECH SOLUTIONS, INC. and CONDUCTIVE TECHNOLOGIES, INC,

Defendants.

Case No. 5:11-CV-4494 EJD

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Hon. Edward J. Davila

Hearing Date: February 21, 2013
Hearing Time: 2:00 p.m.

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND SUMMARY OF ARGUMENT

A threshold issue for this Court to decide, before delving into questions of claim construction, infringement and validity, is whether the doctrine of patent exhaustion prevents Lifescan from dictating that patients who own a glucose monitoring meter in the OneTouch Ultra family of meters use only the OneTouch Ultra Test Strip with that meter. The answer to this question is likely "no," so this motion for preliminary injunction should be denied.

First, by conceding that a necessary limitation of U.S. Pat. No. 7,250,105 ("the '105 Patent") is the insertion of a test strip into a meter, Plaintiffs admit that they cannot prevail on any claim that Defendants[1] directly infringe the '105 Patent by making or selling the Shasta GenStrip. To make out a claim for indirect infringement against Defendants, Plaintiffs must be able to establish direct infringement.

Second, by selling or giving away to consumers OneTouch Ultra Systems, which include, among other things, a meter and several test strips, Plaintiffs exhaust any infringement claims they may have had against persons using such system. To the extent Plaintiffs sell or give away meters not accompanied with test strips, Plaintiffs still have exhausted any infringement claims related to the use of the meters that practice those elements of the '105 Patent that are essential to the invention and the meters have no substantial non-infringing use.

Third, while Plaintiffs affix to the packaging of their systems and meters phraseology that use of the meter is only licensed to practice the '105 Patent with Plaintiffs' test strips, Plaintiffs are not likely to establish the consumer assent necessary to create an enforceable post-sale condition, particularly for those patients who received their OneTouch Ultra Systems and meters free of charge.

Fourth, courts refuse to enforce tying arrangements where, as here, a patentee is trying to extend their patent rights beyond the scope granted by the USPTO. Courts have been particularly loathe to allow tying especially where, as here, the patentee admits power in a relevant market.

[1] "Defendants" collectively refers to Shasta Technologies, LLC ("Shasta"), Instacare Corp. ("Instacare"), Pharmatech Solutions, Inc., ("Pharmatech") and Conductive Technologies, Inc. ("Conductive").

Irrespective of patent exhaustion, the '105 Patent is invalid under 35 U.S.C. §§ 101, 103, and 112. And even if valid, Plaintiffs fail to introduce admissible evidence of their likelihood to prevail on any infringement claim. At best, Plaintiffs' expert assumes infringement because the GenStrip is designed to work with meters in the OneTouch Family of meters. In his same declaration, however, the expert opines that a test strip could be designed to work with Plaintiffs' meters without practicing the '105 Patent. Not only is this expert's opinion not helpful, and therefore inadmissible due to its lack of a rational scientific foundation, the fundamental inconsistency between the bases for the two proffered opinions renders the entire declaration superfluous.

Even if Plaintiffs could demonstrate a likelihood of success, their contention of irreparable harm fails. Plaintiffs must demonstrate that it is the unique method described in the '105 Patent that will drive consumer demand to the GenStrip, and that Defendants use of the *claimed invention* – not merely the sales of a competitive strip – will cause Plaintiff to suffer irreparable harm Plaintiffs do not even try to meet this standard.

II. BACKGROUND

A. LifeScan's OneTouch Ultra System

[2] Relevant portions of the December 21, 2012 volume of the Peter Menziuso Deposition ("December Menziuso Deposition") are attached to the accompanying declaration of John Shaeffer ("Shaeffer Decl.") at Exhibit C. Relevant portions of the January 23, 2013 volume II of the Peter Menziuso Deposition ("January Menziuso Depo.") are attached to Shaeffer Decl. at Exhibit D.

B. The '105 Patent

The origins of the electrochemical glucose biosensors of the type implemented by the OneTouch Ultra system date back to the early 1960s.[3] These systems determine the amount of electrical current generated from the interaction of glucose in whole blood with a glucose oxidizer enzyme, and then correlate that current to a glucose concentration. Wang Decl. at ¶ 7. They rely on disposable test strips printed with a working sensor covered with an enzyme layer. The patient deposits a small sample of blood (typically from a prick of a finger) to the edge of the strip, and the blood is drawn into the strip to the enzyme for the chemical reaction to occur. Current is then measured using connection terminals at the end of the strip, and the measured current is processed and correlated to a glucose concentration. *Id*.

The '105 Patent issued on July 31, 2007, and is a continuation of US Patent No. 6,733,655, which its inventors filed during the development of the OneTouch Ultra System. Wang Decl. at Ex. 4. A problem in the prior art recognized during the development of the OneTouch Ultra system and cited in the '105 Patent was "that inaccurate results are obtained if the working sensor part is not fully covered with blood since then its effective area is reduced." *Id*. at 1:38-40. The inventors noted that various ways for dealing with this problem had been proposed, including adding a plurality of sensors. *Id*. at 1:41-47. The prior art discloses numerous designs of test strips with multiple sensors designed in part to address errors with respect to the reading on a single sensor. The '105 Patent does not present or claim a new test strip. Wang Decl., ¶¶ 9-14. Rather, the '105 Patent identifies as its unique invention a "measuring device [that] compares the current generated by the two working sensor parts and gives an error indication if they are too dissimilar – i.e. the current at one sensor part differs too greatly from what one would expect from considering the current at the other." *Id*., Ex. 4, at Abstract.

After the '105 Patent was allowed (but before it was issued), Lifescan filed a continuation patent application attempting to expand the coverage of the '105 Patent, namely application number 11/772,714 ("the '714 Application"). Wang Decl. at ¶ 9, Ex. 7. The '714 Application claimed the test

[3] *See* Wang, *Electrochemical Glucose Biosensors*, 108 Chem Rev. 814 (2008) a copy of which is attached to the accompanying declaration of Joseph Wang ("Wang Decl.") as Ex. 3.

strip from the '105 Patent, without the associated method steps, and was rejected by the USPTO: (a) for "obviousness-type" double patenting based on the '105 Patent; (b) as being both anticipated by and obvious in view of U.S. Pat. No. 6,258,229 to Winarta; and (c) as obvious in view of 5,120,420 to Nankai. *Id*. at ¶ 10, Ex. 7. Lifescan abandoned the '714 Application following this rejection. *Id*. at ¶¶ 9, 11, Ex. 7.

C. Procedural History

On September 9, 2011, Plaintiffs filed the instant action seeking a declaration from this Court that the GenStrip would infringe, not the '105 Patent, but U.S. Patent Nos. 5,708,247 ("the '247 Patent") and 6,241,862 ("the '862 Patent"). Dkt. No. 1. Both the '247 and '862 Patents claim as a unique layer that sits on top of a working sensor of a glucose test strip. Shaeffer Decl. at Exs. A, B.

In August of 2012 counsel for Plaintiffs informed this Court that, as the result of documents produced by Defendants, they could now prove infringement and intended to immediately seek a preliminary injunction. Rather than follow through with that promise, on October 26, 2012, Plaintiffs sought leave from the Court to amend their Complaint and add the '105 Patent. Dkt. No. 154.

On December 14, 2012, shortly after this Court granted them leave to file their amended complaint, Plaintiffs filed the instant motion seeking a preliminary injunction based on the alleged infringement of the '105 Patent only.

III. LEGAL ARGUMENT

A. Standard For Preliminary Injunction

In patent cases, a plaintiff seeking a preliminary injunction must make a four-fold showing: (1) that it is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in its favor; and (4) that an injunction is in the public interest. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008); *Apple Inc. v. Samsung Electronics Co.*, 695 F.3d 1370, 1373-73 (Fed. Cir. 2012).

B. Plaintiffs Cannot Establish a Reasonable Likelihood Of Success On The Merits

To demonstrate that they have a likelihood of success, Plaintiffs must show that, (1) they will likely prove that Defendants infringe the '105 Patent and (2) their infringement claim will likely withstand Defendants' challenges to the validity and enforceability of the '105 Patent. *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997). In other words, if Defendants raise a "substantial question" concerning validity, enforceability, or infringement (*i.e.*, assert a defense that Plaintiffs cannot show "lacks substantial merit"), the preliminary injunction should not issue. *Id.* The Federal Circuit recently affirmed this test by vacating a preliminary injunction where the district court incorrectly concluded that the defendant failed to raise a substantial question of validity. *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1263 (Fed. Cir. 2012).

Defendants' burden for showing a substantial question of invalidity does not equate to the "clear and convincing" standard required to invalidate a patent at trial. *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1354 (Fed. Cir. 2008). "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Amazon.com*, 239 F.3d at 1359.

1. By Making and Selling the GenStrip, Defendants Do Not Directly Infringe the '105 Patent

Although their brief is far from a model of clarity, Plaintiffs appear to claim that Defendants directly infringe the method described in the '105 Patent by making and selling the GenStrip. Memo. at 8-10. Plaintiffs, however, are well aware from their prior action in this district that the manufacture and sale of a product that allows the practice of a patented method cannot support a claim for direct infringement. *Lifescan Inc. v. Can-Am Care Corp.*, 859 F. 392, 396 (N.D.Cal. 1994) ("it is only the

end-user who use the strips in Lifescan's meters who could possibly directly infringe Lifescan's patented methods"); *see also Ricoh Co. Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1336 (Fed. Cir. 2008) (sale of software containing instructions to perform a patented method does not give rise to a claim for direct infringement). Defendants do not directly infringe the '105 Patent.

2. Since Consumers Likely Can Use GenStrips With Their OneTouch Ultra Monitors Without Directly Infringing the '105 Patent, Plaintiffs Are Not Likely To Prevail On Any Claim of Indirect Infringement

(a) The Acquisition By Consumers Of Either OneTouch Ultra System Or A Meter Alone Exhausts Any Patent Rights Plaintiffs May Have Had With Respect To The Subsequent Use Of That Meter

Plaintiffs assert that it is the "[u]se of the GenStrip in conjunction with Lifescan's OneTouch Ultra meters [that] infringe[s the method described in] claim 3 of the '105 Patent, and [that] Defendants . . . violate the patent statute by inducing and contributing to that infringement." Memo. at 7:6-8. Plaintiffs cannot succeed on any such indirect claim of infringement absent proof that all of the limitations of Claim 3 of the '105 Patent are practiced in a manner that could support a claim for direct infringement. *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 483 (1964)("[I]t is settled that if there is no direct infringement of a patent there can be no contributory infringement."); *see also Met-Coil Systems Corporation v. Korners Unlimited, Inc.*, 803 F.2d 684 (Fed. Cir. 1986) (where Met-Coil's customers cannot infringe the patent, there cannot be a contributory infringement claim); *Akamai Technologies Inc. v. Limelight Networks Inc.*, 692 F.3d 1308 (Fed. Cir. 2012) ("An important limitation on the scope of induced infringement is that inducement gives rise to liability only if the inducement leads to actual infringement.").

Plaintiffs must acknowledge that the disposition of a OneTouch Ultra System without enforceable conditions can extinguish any patent rights practiced by the meter. *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 621 (2008) ("Because the exhaustion doctrine applies to method patents, and because the license authorizes the sale of the components that substantially

embody the patents in suit, the sale exhausts the patents.");[4] *B. Braun Medical, Inc. v. Abbott Laboratories*, 124 F.3d 1419, 1426 (Fed.Cir. 1997) ("As a general matter, [the] unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of the device thereafter."). To the extent some consumers acquire a OneTouch meter alone, exhaustion still applies. "*Quanta* held that exhaustion is triggered by the sale of product that embodies 'essential features of the patented invention' and whose 'only reasonable and intended use [is] to practice the patent.'" *LG Electronics, Inc. v. Hatachi Ltd.*, 655 F.Supp.2d 1036, 1042 (N.D. Cal. 2009) (quoting *Quanta*, 533 U.S. at 630).

(b) Plaintiffs' Distribution Scheme Triggers Patent Exhaustion

A traditional sale is not required to trigger exhaustion, but can include any authorized disposition of the article including discounts or simply giving the article away. *Transcore, LP v. Elec. Transaction Consultants Corp.*, 563 F.3d 1271, 1279 (Fed. Cir. 2009) (exhaustion occurs from terms of settlement agreement); *cf. UMG Recordings, Inc. v. Augusto*, 628 F.3d 1175, 1183 (free disposition of promotional CDs triggered the first sale doctrine under the Copyright Act). Plaintiffs' argument that they give away up to half of their meters as part of a OneTouch Ultra System or alone and sell the others at a discount does not prevent the operation of patent exhaustion post-*Quanta*. *Static Control*

[4] *Quanta* resolved confusion concerning whether the doctrine of patent exhaustion applied to method patents like the '105 Patent. Some courts finding that exhaustion did not extend to method patents would still preclude a patent holder from enforcing method patent claims following the authorized disposition of an article with no non-infringing use, albeit under the nomenclature of an implied license. *See, e.g., LG Electronics, Inc. v. Bizcom Electronics, Inc*., 453 F. 3d 1364, 1370 (Fed. Cir. 2006) *rev'd by Quanta,* 553 at 629-30; ("the sale of a device does not exhaust a patentee's rights in its method claims."); *Carborundum Co. v. Molton Metal Equipment Innovations*, 72 F.3d 872, 878 (Fed. Cir. 1995) (recognizing implied license to practice patent from purchase of unpatented product"); *Lifescan Inc. v. Polymer Technology Intern. Corp*., 1995 WL 271599 *7 (W.D. Wa. 1995) (implied license applies only to method patents). While Plaintiffs separately discuss patent exhaustion and implied license, after *Quanta* and in this context there is no need for such a separate discussion. Finally, in their implied license discussion, Plaintiffs completely mischaracterize the court's holding in *Lifescan Inc. v. Polymer Technology Intern. Corp.* Contrary to Plaintiffs' contention, that court did not reject the existence of an implied license because of the package notice, but expressly left that issue undecided. *Lifescan Inc. v. Polymer Technology Intern. Corp*., 1995 WL 271599 *7 ("whether or not Lifescan's *customers* have an implied license to practice the methods claimed in the two method patents . . . , such a license does not create an implied license for [the defendant] to make and sell the test strips [claimed in a different utility patent]") (emphasis added).

Components, Inc. v. Lexmark Intern. Inc., 615 F.Supp.2d 575, 586 (E.D. Ky. 2009) ("regardless of the fact that Lexmark may not have received full value of it Prebate cartridge, after *Quanta* Lexmark may not invoke patent law in order to enforce its Prebate terms").

(c) The Meters Embody What Is "Inventive" In The '105 Patent

Plaintiffs attempt first to avoid exhaustion by arguing that the OneTouch Ultra meters alone do not "substantially embody" the "essential features" of the invention of the '105 Patent. Plaintiffs argue that it is the test strips and not the meters that substantially embody the invention of the '105 Patent. Memo. at 12:3-5. Plaintiffs first err in ignoring that what most customers first acquire is a OneTouch Ultra System – which includes both a meter and test strips – and not a meter alone. Even accepting Plaintiffs' argument that the meters alone do not practice the "essential features" of the invention,

at 174:22-175:2, 175:17-21, *generally* 162:19-176:13.[5]

For that unidentifiable subclass of customers who acquire OneTouch Ultra meters not as part of a OneTouch Ultra System, it remains Plaintiffs' burden to establish that the meters alone do not "substantially embody" the "essential features" of the invention of the '105 Patent. Plaintiffs must convince this Court that the meters themselves do not carry out what is "the inventive processes" of the '105 Patent to prevail. *Quanta*, 553 U.S. at 634.

Meyerhoff Depo., 144:1-11. However, "[t]he mere fact that a component is *necessary* to practice the patent does not mean that it reflects an *inventive aspect* of the patent . . . ." *LG Electronics, Inc. v. Hitachi Ltd*, 655 F.Supp.2d at 1043 (emphasis in original); *Acco Brands, Inc. v. PC Guardian Anti-Theft Product*, 2008 WL 3915322, *2 (N.D. Cal. 2008) (question of fact as to whether article sold embodied "the critical element of the . . .patent that distinguished it from the prior

[5] True and correct copies of all relevant excerpts from the Meyerhoff Depo. are attached to Exhibit M of the Declaration of Lael Andara ("Andara Decl.").

art"). Plaintiffs want this Court to read *Quanta* such that anything other than "standard components" utilized to practice a method must "substantially embody" the essential features. Memo. at 13:19-20. *Quanta*, however, does not support such a narrow construction. Instead, this Court should look to whether the additional components amount to "a unique feature of the patented system." *LG Electronics, Inc. v. Hitachi Ltd*, 655 F.Supp.2d at 1043. *LG Electronics*, which addressed the same patents at issue in *Quanta*, determined that even though a necessary step in the method was "accomplished by a proprietary (and, by implication non-"standard" chipset)" that "d[id] not mean that the chipset itself emodie[d] an inventive aspect" of the patent-in-suit. *Id.* Because the patent at issue there merely required the two chips to communicate rather than anything unique about their construction, the court concluded that the proprietary nature of the chipset would not defeat exhaustion. *Id.*

The '105 Patent itself, and the prior art discussed below, demonstrate there is nothing unique about a test strip utilizing a plurality of working sensors, or placing each working sensor downstream from the others. Wang Decl. at Ex. 4 at 1:38-48; *infra* at Section III.B.4. The problem and solution identified in the '105 Patent show what Plaintiffs claimed to be unique and inventive about the '105 Patent. The problem "recognized in the art [is] inaccurate results are obtained if the working sensor part is not fully covered with blood." Wang Decl. at Ex. 4 at 1:38-41. One way to solve this problem recognized in the prior art was to utilize a plurality of working sensors and then average the reading to correct for error. Wang Decl., Ex. 12, at 39:26-46; 40:11, 14-16. The '105 Patent's unique feature focuses on its "measuring device['s ability to] compare the current generated by the two working sensor parts and give an error indication if they are two dissimilar." Wang Decl. at Ex. 4 at 2:27-29. Aware that this feature is the "invention" in the '105 Patent, Plaintiffs attempt to construe "measuring device" to be only "a test strip." Memo. at 4:18-19.

Meyerhoff Depo., 144:1-11, 205:19-206:4. For consumers, a meter is necessary to practice the "unique" feature. *Id.*, 174:22-176:13. As in *LG Electronics, Inc.*, what is claimed to be unique is not the characteristics of a necessary article – here a test strip with multiple sensors – but

rather how information from the article is used – *i.e.*, the meter's ability to read differences in the currents generated. Plaintiffs simply have not met their burden of proving a likelihood of success on this element.

(d) OneTouch Ultra Meters Have No Substantial Non-Infringing Use

Plaintiffs do not even attempt to argue that the OneTouch Ultra *System* (which includes a meter and test strips) has any non-infringing use. Instead, again focusing on the unidentified subclass of customer who acquire a OneTouch Ultra meter alone, Plaintiffs bizarrely contend that their meters, standing alone, have a substantial non-infringing use because they could test for glucose without practicing all of the limitations of the '105 Patent. However, Plaintiffs do not even assert that such a test strip even exists.

There is no way to know this from the '105 Patent or its file history. Since on its face the only evidence proffered by Plaintiffs to support a substantial non-infringing use lacks any merit, Plaintiffs have not demonstrated that they are reasonably likely to prevail on this issue.

(e) Plaintiffs Are Not Likely To Prevail On Their Contention That The Post-Sale Condition They Place On The Use Of A One Touch Ultra Meter Is Enforceable

[6] *Compare Lifescan Inc. v. Polymer Technology Intern. Corp.*, 1995 WL 271599 *7 (W.D. Wa. 1995) (Lifescan introduced evidence that the defendant had made a non-infringing use of its test strip).

Plaintiffs are correct that, prior to *Quanta*, it was clear that the "exhaustion doctrine . . . does not apply to an expressly conditional sale or license." *B. Braun*, Inc., 124 F.3d at 1426. Plaintiffs point to the following language on their packaging as precluding operation of the exhaustion doctrine.

> Use of the monitoring device included here is protected under one or more of the following U.S. patents: 7,250,105…. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch® Ultra® Test strips.

Menziuso Decl. at Ex. B. Prior to *Quanta*, courts recognized that any such conditional language was "contractual in nature and subject to antitrust, patent, contract and any other applicable laws, as well as equitable considerations such as patent misuse." *B. Braun*, Inc., 124 F.3d at 1426 (citing *Malinckrodt v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992)); *McCoy v. Mitsubishi Cutlery*, 67 F.3d 917, 920 (Fed. Cir. 1995) ("Whether express or implied, a license is a contract 'governed by ordinary principles of state contract law.'" (quotation omitted)). "Accordingly, conditions that violate some law or equitable considerations are unenforceable" and will not prevent the operation of patent exhaustion. *B. Braun*, Inc., 124 F.3d at 1426. Plaintiffs are well aware from their prior litigation in this District that, even prior to *Quanta*, there existed a question of fact as to whether the language included on their packaging could forestall patent exhaustion. *Lifescan, Inc. v. Cam-Am Corp.*, 859 F.Supp. at 395 ("the Court finds that a triable issue of fact exists with respect to the effectiveness of [Lifescan's] license restriction").

Today, a scholarly debate persists as to whether *Quanta* overruled Federal Circuit law that a conditional sale may prevent operation of the exhaustion doctrine. *Static Control Components, Inc. v. Lexmark Intern.*, 615 F.Supp.2d 575, 585 (E.D. Ky. 2009) (citing academic literature). While the *Quanta* Court did not find that a post-sale restriction had been placed on the article at issue, in *dicta* the Court stated "the authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article." *Quanta*, 553 U.S. at 638. District courts following this language conclude that conditions on a consumer's use of a patented product – as opposed to restrictions on resale – do not forestall patent exhaustion after *Quanta*. *Static Control Components, Inc. v. Lexmark Intern.*, 615

F.Supp.2d at 584 ("Lexmark attempts to reserve patent rights in its products through post-sale restriction on use imposed on its customers. This is what *Quanta* says Lexmark cannot do."); *Keurig Inc. v. Strum Foods, Inc.*, 2012 WL 4049799 *6 (D.Del. Sept. 13, 2012) ("a review of Supreme Court precedent on the law of patent exhaustion 'reveals that the Court has consistently held that patent holders may not invoke patent law to enforce restriction on the postsale use of their patented products.'" (quoting *Static Control*, 615 F.Supp. 2d at 582)).

In *Static Control*, Lexmark, a copier maker, sold toner cartridges to customers at a discount with a disclosure on the packaging that by their purchase customers were agreeing that the cartridges were for single use only. *Id.* at 577. Just as in this case, Lexmark argued that its use restriction should be enforced because consumers acquired the cartridges at a discount in exchange for their agreement on the single use restriction. Rejecting this argument, the *Static Control* Court was "persuaded that, regardless of the fact that Lexmark may not have received the full value of its Prebate cartridges, after *Quanta* Lexmark may not invoke patent law in order to enforce its Prebate terms."[7] *Id.*

Even if this Court chooses not to follow *Static Control*, and concludes that post-sale conditions on use can be enforced after *Quanta*, Plaintiffs' post-sale condition requiring the use of their test strips only with their meters violates basic rules of contract formation and is otherwise unenforceable for the reasons stated below.

(i) Plaintiffs Are Not Likely To Establish Consumer Assent To The Alleged Post-Sale Condition

Under fundamental principles of contract law, LifeScan's purported post-sale condition has no legal effect unless it can show consumers assented to its terms. *UMG Recordings, Inc. v. Augus*to, 628 F. 3d 1175, 1182 (9th Cir. 2011); *see also Jazz Photo Corp. v. International Trade Commission*, 264 F. 3d 1094, 1108 (Fed. Cir. 2001), *cert. denied*, 536 U.S. 950, 122 S. Ct. 2644, 153 L. Ed. 2d 823 (2002) ("meeting of the minds" required for license agreement on product packaging to be

[7] Consistent with other authorities, the *Static Control* Court recognized that Lexmark could still attempt to enforce its conditional use restrictions against its customer through contract law and found questions of fact as to its enforceability under Kentucky contract law. *Static Control Components, Inc. v. Lexmark Intern.*, 615 F. Supp. 2d at 584.

enforceable). Assent must be manifested in some way, by words or other conduct. *SoftMan Products Co., LLC v. Adobe Systems, Inc.*, 171 F. Supp. 2d 1075 (C.D. Cal. 2001).

While the receipt of the meter for free effectuates a sale for purposes of exhaustion, a patient's acquisition can be seen as akin to a gift wholly lacking in the assent necessary to create a contract. *U.S. v. Alcaraz-Garcia*, 79 F.3d 769, 775 (9th Cir. 1996) ("in California, a gift is 'a transfer of personal property, made voluntarily, and without consideration.' Cal. Civ. Code § 1146."); *see also Romero v. Northwest Area Foundation*, 129 Fed.Appx. 337 (9th Cir. 2005) ("It is axiomatic that incidental conditions attached to donative promises do not transform promises of gifts into contracts."). No court anywhere has held a consumer bound to a restrictive covenant imposed by a profit motivated vendor like Lifescan simply from their use of a product they received for free. *Cf. UMG Recordings, Inc*, 628 F. 3d at 1180-81 (not for resale sticker prominently affixed to promotional CD sent through mail is not an enforceable condition).

Irrespective of whether the patient pays for a meter or not, Plaintiffs must at a minimum establish that consumers had notice of the purported post-sale condition and had a meaningful chance to reject it. *Arizona Cartridge Remanufacturers Ass'n, Inc. v. Lexmark International, Inc.*, 421 F. 3d 981, 987-988 (9th Cir. 2005). In *Arizona Cartridge*, printer cartridge manufacturer, Lexmark, offered "Prebate" cartridges to consumers at a discounted price in exchange for agreeing to use the cartridges only once and to return the empty cartridges. *Id*. at 983. The Prebate terms were "clearly marked" on the product's box, which also stated that opening the package or using the product "confirms [the consumer's] acceptance" of the terms. *Id*. at 983. Further, the box also informed consumers that they had the option of returning the unopened cartridge if they did not accept the terms, and that a regular price cartridge not subject to the terms was available for purchase. *Id.* at 983-984. Based upon the district court's findings that consumers had notice of the terms and a chance to reject them before opening the box, the Ninth Circuit concluded that opening the box constituted a consumers' assent. *Id*. at 987. The court expressly distinguished the facts in that case from instances where consumers

lack notice of restrictive conditions at the time of purchase. *Id*. at n. 6 (citing *Step-Saver Data Sys. v. Wyse Tech., Inc*., 939 F. 2d 91, 105 (3d Cir. 1991)).

Here, in contrast to *Arizona Cartridge*, Plaintiffs have offered no evidence that consumers were even aware of the condition on the box at the time of purchase or acceptance of the meter, let alone evidence of a "meeting of the minds." The post-sale condition is contained within a small-print notice on the bottom panel of the box. *See* December Menziuso Decl., Exh. N. Even if Plaintiffs could prove that consumers do in fact read the small print on the bottom of the box, reading a notice on a product's packaging *alone* does not constitute assent. *SoftMan Products* 171 F. Supp. 2d at 1087 (drawing distinction between reading notice on software box stating use subject to license agreement, and agreeing to license terms during installation). Further, there is no evidence that LifeScan offered consumers a chance to reject the post-sale condition by offering the OneTouch meter for sale without restrictions, as Lexmark did in *Arizona Cartridge*. Nor can Plaintiffs argue that consumers' acts of purchasing, accepting, opening, or using the OneTouch monitor manifest their assent to the post-sale condition. In contrast to Lexmark's notice -- which clearly stated that by opening the package, consumers "confirmed" their assent to the terms (421 F.3d at 984) -- Plaintiffs' notice does not require that consumers assent to the post-sale condition at any time before opening or using the meter. *See UMG Recordings*, 628 F. 3d at 1182 (statement "Promotional Use Only – Not for Sale" does not even purport to create a license agreement); *Jazz Photo Corp.*, 264 F.3d at 1108 (safety warnings and efficiency instructions do not create implied conditions upon sale).

(ii) The Alleged Post-Sale Condition Is Otherwise Unenforceable

Even if certain post-sale use restrictions remain enforceable after *Quanta*, and even if Lifescan can establish that patients manifested a meaningful assent to the use restriction, the pending use restriction is unenforceable because allowing its enforcement would effectuate an illicit tying arrangement in violation of Section 2 of the Sherman Act. *Motion Picture Patents Co. v. Universal Film Mfg. Co*., 243 U.S. 502, 511 (1917) (cannot condition sale of patented projector on use with particular film); *Mallinckrodt*, 976 F.2d at 708 (conditions that will effectuate a violation of antitrust law remain unenforceable). "A tying arrangement is a device used by a seller with market power in one product market to extend its market power to a distinct product market." *Cascade Health*

Solutions v. PeaceHealth, 515 F. 3d 883, 971 (9th Cir. 2008). "To accomplish this objective, the seller conditions the sale of one product (the tying product) on the buyer's purchase of a second product (the tied product)." *Id.* Tying arrangement can include either "the simultaneous purchase of two products that are arguably two components of a single product" or "the purchase of unpatented goods over a period of time, a so-called 'requirements tie.'" *Ill. Tool Works Inc. v. Indep. Ink, Inc*., 547 U.S. 28, 44 (2006). "Tying arrangements are forbidden on the theory that, if the seller has market power over the tying product, the seller can leverage this market power through tying arrangements to exclude other sellers of the tied product." *Cascade Health Solutions*, 515 F. 3d at 971.

If, as Plaintiffs likely will insist, the more deferential rule of reason standard governs, the Court must also consider whether Plaintiffs' post-sale use condition actually injures competition. *Brantley v. NBC Universal, Inc*., 675 F.3d 1192, 1197 (9th Cir. 2012). To determine injury, "courts distinguish between tying arrangements in which a company exploits its market power by attempting 'to impose restraints on competition in the market for a tied product' (which may threaten an injury to competition) and arrangements that let a company exploit its market power 'by merely enhancing the price of the tying product' (which does not)." *Id.* (*quoting Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 14, (1984), *abrogated in part on other grounds by Ill. Tool Works Inc.*, 547 U.S. at 42-43 ("a tying arrangement involving patented products" is not entitled to a presumption of market power"); *Rick-Mik Enterprises v. Equilon Enterprises*, 532 F. 3d 963, 971 (9th Cir. 2008) ("The injury is reduced competition.").

Depending on what the customer acquires, either the OneTouch Ultra System or a separate OneTouch Ultra meter is the tying product to which Lifescan ties additional OneTouch Ultra test strip by its post-sale use condition. *See International Salt Co., Inc. v. U.S.*, 332 U.S. 392 (1947) (leasing machine conditioned on use of particular salt); *Motion Picture Patents Co.*, 243 U.S. at 511 (requiring use of particular film with projector); *IBM v. U.S.*, 298 U.S. 131, 138-139 (1936) (illegal to tie patented cards to mechanical card reader). Whether Plaintiffs sell at a discount or simply give them away does not undermine the OneTouch Ultra meter as a distinct tying market. *Nobody in Particular Presents, Inc. v. Clear Channel Communications, Inc.*, 311 F.Supp.2d 1048, 1079-80 (D.Colo. 2004) (recognizing that radio airplay can be the tying market where use of concert venue is the tied product

even though no legal price for airplay). For purposes of opposing this motion, the tying market is the United States market for self-monitoring glucose test meters and the tied market is test strips compatible with meters in the OneTouch Ultra family of meters.

"Not all tying arrangements are illegal. Rather, ties are prohibited where a seller 'exploits,' 'controls,' 'forces,' or 'coerces' a buyer of a tying product into purchasing a tied product." *Rick-Mik Enterprises v. Equilon Enterprises*, 532 F. 3d at 971. "In all of th[e]se instances, the justification for the challenge rested on either an assumption or a showing that the defendant's position of power in the market for the tying product was being used to restrain competition in the market for the tied product." *Ill. Tool Works Inc*., 547 U.S. at 34.

United States Steel Corp. v. Fortner Enterprises, Inc., 429 US 610, 620 (1977) ("As the Court plainly stated in its prior opinion in this case, these decisions do not require that the defendant have a monopoly or even a dominant position throughout the market for a tying product"). "The focus in determining economic power should be whether the seller has sufficient power to raise prices or impose onerous terms 'that could not be expected in a completely competitive market.'" *Moore v. Jas. H. Matthews & Co*., 550 F. 2d 1207, 1215 (9th Cir. 1977) (finding an illegal tying arrangement in mortuary services).

Rosenbrough Monument Co. v. Memorial Park Cemetery, 666 F. 2d 1130, 1143 (8th Cir. 1981) (in reversing a lower court finding no illegal tie, the Eight Circuit found as sufficient proof of market power that "[a]ppellees accounted for 22 percent of the burials performed in the market area in 1978, and the exclusive foundation preparation policy, upon which appellant bases its claim, is uniformly followed by nearly all of the cemeteries in St. Louis.")

The post-sale use condition Plaintiffs seek to impose on patients using OneTouch Ultra meters has no purpose other than to preclude competition for compatible test strips. Courts have long rejected Plaintiffs' contention that use restrictions can legitimately protect goodwill. *IBM v. U.S.*, 298 U.S. 131, 138-139 (1936). In *IBM*, the maker of mechanical tabulation machines appealed an injunction forbidding tying of its card reading machine to use of its patented cards arguing that its machines required precise cards and the company's goodwill would suffer if mechanical problems ensured from the use of a competitor's inferior card. *Id.* Rejecting IBM's goodwill defense, the Supreme Court stated that "[t]he very existence of such restrictions suggests that in its absence a competing article of

equal or better quality would be offered at the same or at a lower price." *Id. (*quoting *Carbice Corp. v. American Patents Development Corp*., 283 U.S. 27, 32, fn. 2 (1931) (further quotations omitted)).

, Plaintiffs' post-sale use condition is unenforceable because Plaintiffs' use condition effectuates an illicit tie by foreclosing competition from the Shasta GenStrip. *Motion Picture Patents Co.*, 243 U.S. at 511; *Brantley*, 675 F.3d 1192 (typical injury to competition from a tying arrangement is the exclusion of other sellers from the tied market).

3. Use of the Shasta GenStrip With Any OneTouch Ultra Meter Would Not Practice the '105 Patent

Plaintiffs' entire motion rests on a false presumption, that the OneTouch Ultra System practices the '105 Patent. An express limitation of the '105 Patent, however, is that the electric current measured at the working sensor part is proportional to the concentration of glucose in the test sample. *Wang Decl., Ex. 4* at 1:34-35; 7:13-15.

A direct infringement of a method claim requires a showing that every step of the claimed method has been practiced. *Meyer Intellectual Properties Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1366 (Fed. Cir. 2012). Among the other steps set forth in the claims of the '105 Patent is a step in claim 1 (and thus in all claims since claims 2 and 3 depend from claim 1) that requires "measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid." *See Id.*, Ex. 4 at 7:13-15. Since OneTouch Ultra meters do not measure an electric current in this manner Plaintiffs' infringement claim must fail.

U.S. Pat. No. 4,655,880 to Liu and U.S. Pat. No. 5,288,636 to Pollmann correctly describe the relationship between current and glucose concentration. Wang at ¶¶ 25-26. Much different from the '105 Patent, these references correctly do not provide that measured current is proportional to glucose concentration. Instead, Pollmann ('636) repeatedly says that measured current can be correlated to the glucose concentration. *See, e.g.*, Wang Decl., Ex. 10 at Abstract; 1:29-31; 2:40-43; 4:47-49; 10:26-27. And Liu ('880) provides extensive explanation about differences in measured current being proportionally representative of glucose concentration. *See, e.g.*, Wang Decl., Ex. 9 at 2:47-51; 4:10-18; 8: 1-54. The sensor arrangement of Liu ('880) is different from that in the '105 Patent since enzyme is only associated with one working electrode in Liu ('880). However, the point remains that

processing of measured current must occur before any proportionality to glucose concentration can occur.

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4. The '105 Patent is Invalid Under 35 U.S.C. § 103 Due To Prior Art

To obtain a preliminary injunction, it is the movant's burden to establish that the non-movant's invalidity arguments "lack substantial merit." *Everett Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, 573 F. Supp. 2d 855, 860 (D.N.J. 2008). "In other words, if Defendant raises substantial questions regarding invalidity, Plaintiff is not entitled to a preliminary injunction." *Id*. (*citing Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) *and Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001)). The non-movant's burden to show a substantial question of invalidity does not equate to the "clear and convincing" standard required to invalidate a patent at trial. *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1354 (Fed. Cir. 2008) ("a showing of a substantial question of invalidity requires less proof than the clear and convincing standard to show actual invalidity"). "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Amazon.com*, 239 F.3d at 1359.

A patent is invalid for obviousness under 35 U.S.C. § 103 "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Obviousness is a question of law based on underlying findings of fact. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010). The underlying factual inquiries include: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) any relevant secondary considerations. *Id.*

Various rationales may be used to find a patent claim obvious. For example, a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). And when a work is available in one field, design incentives and other market forces can prompt variations of it, either in the same field or in another. *Id.* at 417. Rearranging parts in a manner that does not change operation

of the device is also not a patentable improvement. *In re Japikse*, 181 F.2d 1019, 1023 (C.C.P.A. 1950). Still further, where a skilled artisan merely pursues known options from a finite number of identified, predictable solutions, the result was merely obvious to try. *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009).

A court must ask whether the claimed improvement is more than the predictable use of prior art elements according to their established functions. *KSR*, 550 U.S. at 417. To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. *Id.* at 418. Analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, however, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ. *Id.* The legal determination of obviousness may include recourse to logic, judgment, and common sense. *Wyers*, 616 F.3d at 1239-40.

After the '105 Patent was allowed (but before it was issued), Lifescan filed the '714 Application hoping to expand the coverage of the '105 Patent. USPTO, however, rejected the '714 Application: (a) for "obviousness-type" double patenting based on the '105 Patent; (b) as being both anticipated by and obvious in view of U.S. Pat. No. 6,258,229 to Winarta; and (c) as obvious in view of 5,120,420 to Nankai. Wang Decl., ¶ 10, Ex. 7. Lifescan abandoned the '714 Application following its rejection. *Id*. at ¶ 11, Ex. 7.

An "obviousness-type" double patenting rejection arises when the claims of a pending application are not identical to issued claims in a related patent, but nevertheless fail to be patentably distinct from the issued claims. *See, e.g., In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998); Manual of Patent Examining Procedure at § 804. So, in effect, the USPTO found that the now-abandoned '714 Application presented claims that were patentably indistinguishable from the claims in the '105 Patent, and found that the claims of the '714 Application were not patentable based on prior art that was not reviewed before the '105 Patent was allowed. Lifescan's decision to abandon the '714 Application rather than traverse the rejections, places a cloud over the '105 Patent. When coupled

with other references not considered during prosecution of the '105 Patent, Defendants have raised a "substantial question" concerning validity and a preliminary injunction would accordingly be inappropriate. *See Genentech*, 108 F.3d at 1364; *Sciele Pharma*, 684 F.3d at 1263.

(a) Obviousness Ground 1.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Winarta ('229) in view of U.S. Pat. No. 6,175,752 to Say.[10] Winarta ('229) discloses a test strip that includes all of the features of the "disposable test strip" component of the measuring device of claim 1. Winarta ('229) also discloses applying the sample liquid to the measuring device. *See* Wang Decl., Ex. 11 at 5: 59-62; 10:1-67.

Say ('752) discloses that readings should be taken from multiple electrodes and compared to one another to identify errors. *See id.*, Ex. 12 at 39: 26-46; 40:11 and 14-16. Because the test strip of Winarta ('229) is capable of taking multiple measurements (i.e., using the first working sensor part W and the second working sensor part Wo), it would have been obvious to take multiple measurements and obtain an average as taught by Say ('752). Wang Decl., ¶ 35. This would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. *Id.* Because the measurements using the Winarta ('229) device would be the same as the measurements taken in the '105 Patent since the devices are the same, use of the Winarta ('229) device would necessarily "measure an electric current… proportional to the concentration of said substance" if that element is not invalid under 35 U.S.C. § 112. *Id.*

When the comparison in Say ('752) reveals that the difference in readings is outside a predetermined threshold level, the patient is alerted that the sensor is defective. *See* Wang Decl., Ex. 12 at 39: 26-46; 40:11. Alerting users of the Winarta ('229) device of defects would have been obvious in light of the teachings of Say ('752). Wang Decl., ¶ 36. This would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. *Id.*

(b) Obviousness Ground 2.

[10] A claim chart showing application of Winarta ('229) and Say ('752) to claim 1 is attached to the Wang Decl. at Ex. 13.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Winarta ('229) in view of U.S. Pat. No. 5,004,998 to Horii.[11]

In addition to Winarta ('229) as already described, Horii ('998) teaches that multiple measurements should be taken to identify errors. It would have been obvious for the same reason discussed above to take multiple measurements as taught by Horii ('998). *See* Wang Decl., Ex. 14 at Abstract; FIG. 2. This would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. *Id*. at ¶ 41. Because the measurements using the Winarta ('229) device would be the same as the measurements taken in the '105 Patent since the devices are the same, use of the Winarta ('229) device would necessarily "measure an electric current…proportional to the concentration of said substance" if that element is not invalid under 35 U.S.C. § 112. *Id*. at ¶ 40.

Horii ('998) further discloses comparing the measurements to establish a difference parameter, and then giving an indication of an error if the difference parameter is greater than a predetermined threshold. *See id.*, Ex. 14 at Abstract; 3:41-5:9; FIG. 2. This would also be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. Wang Decl., ¶ 41.

(c) Obviousness Ground 3.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Winarta ('229) in view of U.S. Pat. No. 5,791,344 to Schulman.[12] In addition to Winarta ('229) and Horii ('998) as already described, Schulman ('344) teaches that multiple measurements should be taken and compared to identify errors. It would have been obvious for the same reasons discussed above to take multiple measurements as taught by Schulman ('344). *See* Wang Decl., Ex. 16 at 3:17-28.

(d) Obviousness Ground 4.

[11] A partial claim chart showing application of Winarta ('229) and Horii ('998) to claim 1 is attached as Ex. 15 to Wang Decl. Elements not specifically listed are met by Winarta ('229) as set forth above in Obviousness Ground 1.

[12] A partial claim chart showing application of Winarta ('229) and Schulman ('344) to claim 1 is attached hereto as Wang Decl., Ex. 17. Elements not specifically listed are met by Winarta ('229) as set forth above in Ground 1.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Winarta ('229) in view of: (a) U.S. Pat. No. 5,672,256 to Yee; and (b) Ramakant Khazanie, Statistics in a World of Applications (1997) ("Khazanie").[13] In addition to Winarta ('229) as already described Yee ('256) discloses that, due for example to the construction methods for test strips, error can be expected in test results. *See* Wang Decl., Ex. 18 at 1:21-36. To counter that error, Yee ('256) teaches that multiple measurements should be taken and averaged together. It would have been obvious for the same reasons discussed above to take multiple measurements and obtain an average as taught by Yee ('256). *Id.* at 1:48-51; 2:34-41 and 49-56.

While taking multiple readings with the device of Winarta ('229) is thus an obvious step, Khazanie teaches that simply averaging the values of collected data without doing more is an undesirable practice. For example, Khazanie says that "Variability of values in data collected is a very common phenomenon, and its importance should be acknowledged." Wang Decl., Ex.19 at p. 101. To obtain a better understanding of the collected data, either the mean deviation—or even more preferably the standard deviation—should be computed. *Id.* at pp. 103-105. Thus, when considered in view of the Winarta ('229) and Yee ('256) combination set forth above, Khazanie teaches that the electric current from each of the working sensor parts should be compared to establish a difference parameter (i.e., a mean deviation or a standard deviation). Wang Decl., ¶ 52. This would be nothing more than the combination of prior art elements according to known methods to yield predictable results, and Khazanie's teaching further would have led one of ordinary skill to modify the prior art references to include this step. *Id*.

Finally, because Winarta ('229) teaches that it is important to obtain accurate glucose readings, (*see* Wang Decl., Ex. 11 at 1:13-19; 3:36-37, and also because Yee ('256) teaches that there is a range of errors that is impermissible, *see* id., Ex. 18 at 1:33-53), it would have been obvious to indicate that an error has occurred if the difference parameter is greater than a predetermined threshold (i.e., if the

[13] A claim chart showing application of Winarta ('229), Yee ('256), and Khazanie to claim 1 is attached to Wang Decl., Ex. 20. A copy of Ramakant Khazanie, Statistics in a World of Applications (1997) is attached to Wang Decl., Ex. 19. Elements not specifically listed are met by Winarta ('229) as set forth above in Obviousness Ground 1.

readings are not sufficiently accurate, meaning that the error is impermissible). Wang Decl., ¶ 53. One of ordinary skill in the art would have been motivated to provide the indication of an error based on the teachings of Winarta ('229), the disclosure of Yee ('256), and common sense. *Id.*

(e) Obviousness Ground 5.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Winarta ('229) in view of William Lichten, Data and Error Analysis in the Introductory Physics Laboratory (1996) ("Lichten").[14] In addition to Winarta ('229) as already described, Lichten discloses that, to improve test results, "Common sense tells you to take the average of several elements, called the arithmetic mean or mean," and for the reasons discussed above it would have been obvious to take multiple measurements and obtain an average as taught by Lichten. Wang Decl., Ex. 21 at p. 2; ¶ 56.

While taking multiple readings with the device of Winarta ('229) is thus an obvious step, Lichten teaches that simply averaging the values of collected data without doing more is incomplete. Instead, an estimate of error in the measurement should be obtained. *See id*., Ex. 21 at p. 3. According to Lichten, a "handy measure" of the error is the average deviation from the mean. *Id.* at ¶ 57. Thus, when considered in view of Winarta ('229), Lichten teaches that the electric current from each of the working sensor parts should be compared to establish a difference parameter (i.e., the average deviation). *Id.* This would be nothing more than the combination of prior art elements according to known methods to yield predictable results, and Lichten's teaching further would have led one of ordinary skill to modify Winarta ('229) to include this step. *Id.*

Finally, because Winarta ('229) teaches that it is important to obtain accurate glucose readings, *see id.*, Ex. 11 at 1:13-19; 3:36-37, it would have been obvious to indicate that an error has occurred if the difference parameter is greater than a predetermined threshold (i.e., if the readings are not sufficiently accurate). *Id*., ¶ 58. One of ordinary skill in the art would have been motivated to provide the indication of an error based both on the teachings of Winarta ('229) and common sense. *Id.*

(f) Obviousness Ground 6.

[14] A partial claim chart showing application of Winarta ('229) and Licthen to claim 1 is attached to the Wang Decl. as Exhibit 22. Elements not specifically listed are met by Winarta ('229) as set forth above in Obviousness Ground 1.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Nankai ('420) in view of Say ('752). Nankai ('420) discloses a test strip (or "measuring device") that includes all of the features of the measuring device of claim 1, except it does not explicitly place the reference sensor upstream of the working sensor parts.[15] However, such configuration is merely an unpatentable rearrangement of parts; even Plaintiffs' expert has admitted that there is no operational difference between various arrangements of the sensor parts. *See* Meyerhoff Declaration at ¶¶ 45-46. Further, Nankai ('420) specifically teaches that the shape and arrangement of the sensors may vary. *See* Wang Decl., Ex. 5 at 8:47-52. So the claimed arrangement would be one of a finite number of identified, predictable solutions having a reasonable expectation of success (and thus obvious to try). Wang Decl., ¶ 60.

Nankai ('420) also discloses applying the sample liquid to the measuring device. *See id.*, Ex. 5 at 8:25-30. Nankai further teaches that multiple measurements should be taken and averaged together. *Id.* at 8:11-14 and 30-46.

Say ('752) discloses that when readings are taken from multiple electrodes, they should be compared to one another to identify errors. *See id.*, Ex. 12 at 39:26-46; 40:11 and 14-16. Incorporating this into Nankai ('420) would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. Wang Decl., ¶ 62. Because the measurements using the Nankai ('420) device would correspond to the measurements taken in the '105 Patent since the devices are essentially the same, use of the Nankai ('420) device would necessarily "measure an electric current…proportional to the concentration of said substance" if that element is not invalid under 35 U.S.C. § 112. *Id.*

When the comparison in Say ('752) reveals that the difference in readings is outside a predetermined threshold level, the patient is alerted that the sensor is defective. *See id.*, Ex. 12 at 39:26-46; 40:11. Alerting users of the Nankai ('420) device of defects would have been obvious in light of the teachings of Say ('752). *Id.*, ¶ 63. This would be nothing more than the use of a known technique to improve similar devices/methods in the same way; the results would be predictable. *Id.*

[15] A claim chart showing application of Nankai ('420) and Say ('752) to claim 1 is attached as Exhibit 23 to the Wang Decl.

(g) Obviousness Ground 7.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Nankai ('420) in view of Schulman ('344). Nankai ('420) is discussed above in Ground 6.[16]

Schulman ('344) teaches that multiple measurements should be taken to identify errors. *See* Wang Decl., Ex. 16 at 3:17-28. Incorporating this into Nankai ('420) would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. Wang Decl., ¶ 69. Because the measurements using the Nankai ('420) device would correspond to the measurements taken in the '105 Patent since the devices are essentially the same, use of the Nankai ('420) device would "measure an electric current…proportional to the concentration of said substance" if that element is not invalid under 35 U.S.C. § 112. *Id.*

Schulman ('344) further discloses comparing the measurements to establish a difference parameter, and then giving an indication of an error if the difference parameter is greater than a predetermined threshold. *See id.*, Ex. 16 at 3:17-28. This would also be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. *Id.*, ¶ 70.

(h) Obviousness Ground 8.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Nankai ('420) in view of Khazanie. Nankai ('420) is discussed above in Obviousness Ground 6.[17]

Khazanie teaches that simply averaging the values of collected data without doing more is an undesirable practice. For example, Khazanie says that "Variability of values in data collected is a very common phenomenon, and its importance should be acknowledged." Wang Decl., Ex. 19 at p. 101. To obtain a better understanding of the collected data, either the mean deviation—or even more preferably the standard deviation—should be computed. *Id.* at pp. 103-105. Thus, when considered

[16] A partial claim chart showing application of Nankai ('420) and Schulman ('344) to claim 1 is attached as Exhibit 24 to the Wang Decl. Elements not specifically listed are met by Nankai ('420) as set forth above in Obviousness Ground 6.

[17] A partial claim chart showing application of Nankai ('420) and Khazanie to claim 1 is attached as Exhibit 25 to the Wang Decl. Elements not specifically listed are met by Nankai ('420) as set forth above in Obviousness Ground 6.

in view of Nankai ('420), Khazanie teaches that the electric current from each of the working sensor parts should be compared to establish a difference parameter (i.e., a mean deviation or a standard deviation). Wang Decl., ¶ 75. This would be nothing more than the combination of prior art elements according to known methods to yield predictable results, and Khazanie's teaching further would have led one of ordinary skill to modify Nankai ('420) to include this step. *Id*. Because the measurements using the Nankai ('420) device would correspond to the measurements taken in the '105 Patent since the devices are essentially the same, use of the Nankai ('420) device would necessarily "measure an electric current…proportional to the concentration of said substance" if that element is not invalid under 35 U.S.C. § 112. *Id*.

Finally, because Nankai ('420) teaches that it is important to obtain accurate glucose readings, *see id.,* Ex. 5 at 1:18-19; 2:64; 4:1-2; 8:43, it would have been obvious to indicate that an error has occurred if the difference parameter is greater than a predetermined threshold (i.e., if the readings are not sufficiently accurate, meaning that the error is impermissible). Wang Decl., ¶ 76. One of ordinary skill in the art would have been motivated to provide the indication of an error based on the teachings of Nankai ('420) and common sense. *Id*.

(i) Obviousness Ground 9.

Claim 1 is invalid under 35 U.S.C. § 103 as obvious over Nankai ('420) in view of Lichten. Nankai ('420) is discussed above in Ground 6.[18]

Lichten teaches that simply averaging the values of collected data without doing more is incomplete. Instead, an estimate of error in the measurement should be obtained. *See* Wang Decl., Ex. 21 at p. 3. According to Lichten, a "handy measure" of the error is the average deviation from the mean. *Id.* Thus, when considered in view of Nankai ('420), Lichten teaches that the electric current from each of the working sensor parts should be compared to establish a difference parameter (i.e., the average deviation). Wang Decl., ¶ 81. This would be nothing more than the combination of prior art elements according to known methods to yield predictable results, and Lichten's teaching further

[18] A partial claim chart showing application of Nankai ('420) and Lichten to claim 1 is attached as Exhibit 26 to the Wang Decl. Elements not specifically listed are met by Nankai ('420) as set forth above in Obviousness Ground 6.

would have led one of ordinary skill to modify Nankai ('420) to include this step. *Id*. The measurements using the Nankai ('420) device would correspond to the measurements taken in the '105 Patent since the devices are essentially the same. *Id*. Because Nankai ('420) teaches that it is important to obtain accurate glucose readings, *see id*., Ex. 5 at 1:18-19; 2:64; 4:1-2; 8:43, it would have been obvious to indicate that an error has occurred if the difference parameter is greater than a predetermined threshold (i.e., if the readings are not sufficiently accurate, meaning that the error is impermissible). *Id*., ¶ 82.

(j) Obviousness Ground 10.

Claim 1 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 6-9 above, further in view of Yee ('256), respectively.[19] Yee ('256) discloses that the arrangement of electrodes does not affect their characteristics. *See* Wang Decl., Ex. 18 at 2:11-13. This further confirms that it would be obvious to place the reference sensor upstream of the working sensor parts, as set forth in claim 1 and the claim chart below. Wang Decl., ¶ 83.

(k) Obviousness Ground 11.

Claim 1 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 6-9 above, further in view of Winarta ('229), respectively.[20] Winarta ('229) discloses placing the reference sensor part R upstream from the working sensor parts W, Wo and unidirectional flow as claimed. *See* Wang Decl., Ex. 11 at 5: 59 – 6:10; 7:23-25; FIG. 2. Incorporating this would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. Wang Decl., ¶ 85.

(l) Obviousness Ground 12.

[19] A partial claim chart showing application of Yee ('256) to claim 1 is attached as Exhibit 27 to the Wang Decl. Elements not included in the chart are met as set forth above in Obviousness Grounds 6-9.

[20] A partial claim chart showing application of Winarta ('229) to claim 1 is attached as Exhibit 28 to the Wang Decl. Elements not included in the chart are met as set forth above in Obviousness Grounds 6-9.

Claim 1 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 1-11 above, further in view of U.S. Pat. No. 6,540,891 to Stewart, respectively.[21] Stewart ('891) discloses that the glucose meters typically used with disposable test strips have electronic features designed to detect invalid test results and report an error condition. *See* Wang Decl., Ex. 29 at 11:18-23. Incorporating this feature from Stewart ('891) would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. Wang Decl., ¶ 87.

(m) Obviousness Ground 13.

Claim 1 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 1 and 3-12 above, further in view of Horii ('998), respectively.[22] Horii ('998) teaches giving an indication of an error if a difference parameter is greater than a predetermined threshold. *See* Wang Decl., Ex. 14 at Abstract; 4:8-16; 5:5-9; FIG. 2. Incorporating this feature from Horii ('998) would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. Wang Decl., 89.

(n) Obviousness Ground 14.

Claim 2 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 1-5 above. Winarta ('229) further teaches measuring the current after a predetermined time following application of the sample. *See* Wang Decl., Ex. 11 at 4:1-4. Thus, in the combinations of references set forth above in Grounds 1-5, the current would be measured at each working sensor part after a predetermined time following application of the sample. Wang Decl., ¶ 91.

(o) Obviousness Ground 15.

Claim 2 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 6-10. Nankai ('420) further teaches measuring the current after a predetermined time following application of the sample. *See* Wang Decl., Ex. 4 at 5:42-49; 6:29-35; 9:31-38; 11:16-26. Thus, in the combinations of

[21] A partial claim chart showing application of Stewart ('891) to claim 1 is attached as Exhibit 30 to the Wang Decl. Elements not included in the chart are met as set forth above in Obviousness Grounds 1-11.

[22] A partial claim chart showing application of Horii ('998) to claim 1 is attached as Exhibit 31 to the Wang Decl. Elements not included in the chart are met as set forth above in Grounds 1 and 3-12.

references set forth above in Grounds 6-10, the current would be measured at each working sensor part after a predetermined time following application of the sample. Wang Decl., ¶ 92.

(p) Obviousness Ground 16.

Claim 2 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 12-13. For those grounds that include Winarta ('229), Winarta ('229) further teaches measuring the current after a predetermined time following application of the sample. *See* Wang Decl., Ex. 11 at 4:1-4. Thus, in the combinations of references set forth above in Grounds 12-13 that include Winarta ('229), the current would be measured at each working sensor part after a predetermined time following application of the sample. Wang Decl., ¶ 94.

For those grounds that include Nankai ('420), Nankai ('420) further teaches measuring the current after a predetermined time following application of the sample. *See id.*, Ex. 5 at 5:42-49; 6:29-35; 9:31-38; 11:16-26. Thus, in the combinations of references set forth above in Grounds 12-13 that include Nankai ('420), the current would be measured at each working sensor part after a predetermined time following application of the sample. *Id.*, ¶ 95.

(q) Obviousness Ground 17.

Claim 2 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 1-13 above, further in view of U.S. Pat. No. 6,004,441 to Fujiwara, respectively. Fujiwara ('441) teaches measuring the current after a predetermined time following application of the sample, to allow the glucose to oxidize. *See* Wang Decl., Ex. 32 at 3:23-33. Incorporating the pause from Fujiwara ('441) into the respective combinations would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable. *Id.*, ¶ 97. Thus, in the respective combinations of references, the current would be measured at each working sensor part after a predetermined time following application of the sample. *Id.*

(r) Obviousness Ground 18.

Claim 3 is invalid under 35 U.S.C. § 103 as set forth in Obviousness Grounds 14-17. For those grounds that include Winarta ('229), Winarta ('229) further teaches that the substance to be measured is glucose. *See, e.g.*, Wang Decl., Ex. 11 at 3:36-39; 10:1-11. Thus, each of the working

sensor parts in those respective combinations of references generates charge carriers in proportion to the concentration of glucose in the sample liquid. *Id*., ¶ 99.

For those grounds that include Nankai ('420), Nankai ('420) further teaches that the substance to be measured is glucose. *See, e.g.,* Nankai ('420) at col. 3, line 65 to col. 4, line 4. Thus, each of the working sensor parts in those respective combinations of references generates charge carriers in proportion to the concentration of glucose in the sample liquid. *Id*., ¶ 100.

5. The '105 Patent is Invalid Under 35 U.S.C. §§ 101 and 112.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation". *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). A claimed invention having an inoperable or impossible claim limitation may lack utility under 35 U.S.C. § 101 and certainly lacks an enabling disclosure under 35 U.S.C. § 112. *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1348 (Fed. Cir. 2001). When a claim itself recites incorrect science in one limitation, the entire claim is invalid. *Id.* at 1349.

Lifescan's own formula used in its devices shows that measured current is not proportional to a concentration of glucose, as discussed in detail above in Section III.B.3. The science set forth in the claims of the '105 Patent is simply incorrect; no known device/method can "measure an electric current…proportional to the concentration of said substance" as required by all claims of the '105 Patent, and especially not without undue experimentation. Wang Decl., ¶¶ 22-28. Accordingly, all claims of the '105 Patent must be found invalid for lacking enablement as required by 35 U.S.C. § 112, as well as lacking utility under 35 U.S.C. § 101. *See EMI Group*, 268 F.3d at 1348.

B. Plaintiffs Fail To Establish Irreparable Harm

Irreparable harm may not be presumed based on a finding of patent infringement. *Apple, Inc. v. Samsung Electronics Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) (hereinafter *Apple I*). The moving party "must make a clear showing that it is at risk of irreparable harm, which entails showing a likelihood of substantial and immediate irreparable injury." *Apple Inc. v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) (citation omitted) (hereinafter *Apple II*).

1. Patentees Must Establish Irreparable Harm Because of the Infringement, Not Because of Competing Sales

To satisfy the irreparable harm element, a patentee must prove a causal nexus between the infringement and the harm. The Federal Circuit very recently elaborated:

> [T]he patentee must also establish that the harm is sufficiently related to the infringement . . . 'To show irreparable harm, it is necessary to show that the infringement caused harm in the first place. Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature. If the patented feature does not drive the demand for the product, sales would be lost even if the offending feature were absent from the accused product. Thus, a likelihood of irreparable harm cannot be shown if sales would be lost regardless of the infringing conduct.' . . . In other words, it may very well be that the accused product would sell almost as well without incorporating the patented feature.

Apple II, 695 F.3d at 1374 (*quoting Apple I*, 678 F.3d at 1324).

Lifescan must make a causal showing that the invention claimed by the '105 Patent "drives consumer demand for the accused product." *Apple II*, 695 F.3d at 1375. "Only viewed through the prism of the causal nexus analysis will the irreparable harm allegations reflect a realistic sense of what the patentee has at stake." *Id.*; s*ee also Apple, Inc. v. Motorola, Inc.*, 869 F.Supp.2d 901, 920 (N.D. Ill. 2012) (Posner, J.) (patentee failed to establish that "infringement of *these* claims (if they were infringed) reduced" sales or market share) (emphasis in original); *Apple II*, 695 F.3d at 1376-77 (reversing grant of injunction where patentee failed to show that "consumers buy the [accused product] because it is equipped with the apparatus claimed in the" patent in suit).

2. LifesScan Failed to Offer Any Evidence that the Patented Technology "Drives Consumer Demand" for the GenStrip

Lifescan failed to offer any evidence or argument suggesting that "consumers buy [GenStrips] because [they are] equipped with the apparatus claimed" in the'105 Patent. *Apple II*, 695 F.3d at 1376. Indeed, consumers interested in practicing the '105 Patent (no one) would never purchase GenStrips.

[23] Lifescan's advertisements assert that the "DoubleSure Technology" is embedded in the test strips, not the monitors. *See* December Menziuso Decl., Ex. B ("The OneTouch Ultra Blue Test Strip with

3. Lost Sales or Market Share are not Irreparable Injuries

Even if Lifescan had provided evidence to support the harm that it speculates might occur, those harms could be remedied with money damages and therefore are not irreparable. *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996) (no irreparable harm where monetary damages are an adequate); *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990); *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, 2007 WL 2669338, *15 (D.N.J. September 6, 2007) ("Any economic harm that Plaintiffs might incur is not irreparable because Defendants can

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DoubleSure Technology"), Ex. C ("Only OneTouch Ultra Blue Test Strips have DoubleSure Technology inside"), Ex. D ("DoubleSure Test Strip Technology"), Ex. F ("The test strip with a second opinion built right in").

pay damages to satisfy any reasonable judgment awarded to Plaintiffs if Plaintiffs ultimately prevail at trial."). "[L]oss of sales, profits or market share does not necessarily establish irreparable harm." *McDavid Knee Guard, Inc. v. Nike USA, Inc.*, 683 F. Supp. 2d 740, 748 (N.D.Ill. 2010). "Proof of lost market share and lost sales alone are insufficient to establish irreparable harm...." *FieldTurf USA, Inc. v. Astroturf, LLC*, 725 F. Supp. 2d 609, 617 n.3 (E.D. Mich. 2010). "Both loss of market share and price erosion are economic harms and are compensable by money damages." *Novartis Pharm. Corp.*, 2007 WL 2669338, *14; *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 692 F. Supp. 2d 805, 821 (N.D. Ohio 2010).

The Federal Circuit has refused to find lost sales sufficient to demonstrate irreparable harm, because "acceptance of that position would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances." *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (citation omitted); *Illinois Tool Works Inc.*, 906 F.2d at 681 (to assume pretrial sales of infringing products cause irreparable harm would "disserve the patent system"). "Further, neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21 v. US*, 930 F.2d 867, 871 (Fed. Cir. 1991) (citation omitted).

Lifescan's authority, which describes when lost sales or market share can be considered irreparable harm, is entirely inapposite. In *Celsis in Vitro, Inc. v. Cellzdirect, Inc.*, the Federal Circuit upheld a district court's finding of irreparable harm where the patentee offered unrebutted expert testimony that incorporated "specific financial records." 664 F.3d 922, 930 (Fed. Cir. 2012). The patentee offered evidence that its products were moving from their "growth phase" to their "mature phase," in which revenues would be at their peak. In *Abbot Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008), the Federal Circuit affirmed the irreparable harm finding without describing the evidence upon which the district court relied. These cases are easily distinguishable from the instant case, where Lifescan failed to submit any financial records and where it is the non-moving party that has offered unrebutted expert testimony. *See Credit Bureau Connection, Inc. v. Pardini*, 2010 U.S. Dist. LEXIS 78345, 2010 WL 2737128 (E.D. Cal. July 12, 2010) (finding that

plaintiff failed to carry its burden of showing likelihood of success when facts were equally in dispute by competing declarations).

The unsupported conclusions set forth in a declaration by Peter Menziuso to establish lost sales and market share cannot alone establish irreparable harm. *See, e.g.*, Menziuso Decl., ¶¶ 22-25.[24] *Caribbean Marine Serv. Co., Inc. v. Baldrige*, 844 F.2d 668, 674 (9th Cir.1988) ("A plaintiff must do more than merely allege imminent harm sufficient to establish standing; a plaintiff must *demonstrate* immediate threatened injury as a prerequisite to preliminary injunctive relief.") (emphasis in original); *Am. Passage Media Corp. v. Cass Commc'n, Inc.*, 750 F.2d 1470, 1473 (9th Cir.1985) (vacating preliminary injunction where the movant's declarations were "conclusory and without sufficient support in facts").

[24] Lifescan questions Defendants' ability to pay a damage award. Memo. at 18:10-26. Its argument is specious given that, elsewhere, Lifescan asserts that Defendants would earn hundreds of millions of dollars a year if an injunction is not awarded. Memo. at 17:14-20. Without more to offer than conclusions, Lifescan cannot credibly assert that Defendants would both make hundreds of millions of dollars and that Defendants would be insolvent and unable to pay a jury award.

C. The Balance Of Equities and the Public Interest Favor Denying an Injunction

An injunction would be catastrophic for the Defendants and would harm the public in a manner that far outstrips any possible harm to Plaintiffs should the injunctive relief Plaintiffs seek not be granted. Defendants invested significant (for them) time and money into obtaining FDA approval for their test strip. Immediately upon obtaining approval, Defendants ramped up production efforts to get their products to market. Similarly, the public would be denied a low cost alternative to the monopoly prices of the OneTouch Ultra strip.[26] As the Supreme Court directed in *Winter*, "[i]n exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter v. Natural Res. Def. Council*, *supra*, 555 U.S. at 24.

Plaintiffs have not shown they will suffer any harm comparable to that they seek to impose on Defendants and the public if Defendants are permitted to sell the GenStrip. Instead, they hypothesize about possible consumer confusion and damage to their "goodwill." *Almaden Vineyards, Inc.*, 1994 WL 564610, *5 (N.D. Cal. Sept. 30, 1994) (denying preliminary injunction where defendant would be left with $800,000 worth of unusable promotional materials and plaintiff merely alleged loss of goodwill). Moreover, Lifescan waited until after Defendants obtained FDA approval to seek an injunction. "[I]t appears that [Lifescan] waited until it would be most harmful to [Defendants] to seek this injunction." *Hologic, Inc. v. Senorx, Inc.*, 2008 WL 1860035 (N.D. Cal. 20008) (denying request for preliminary injunction filed immediately after FDA approval; request was found to be "tactical").

[26] The monopoly market for test strips has resulted in hyper-inflated prices for test strips, which is against the public interest. *See, e.g., Calvin Klein Cosmetics Corp.v. Lenox Laboratories, Inc.*, 815 F.2d 500, 505 (8th Cir. 1987) (reversing preliminary injunction where district court did not account for "strong public interest in lowest possible prices" and an interest in avoiding monopolies*); International Jensen, Inc. v. Metrosound U.S.A., Inc.*, 4 F.3d 819, 827 (9th Cir. 1993) (affirming denial of an injunction and accepting district court finding that injunction would deprive consumers of a choice of products); *Active Network, Inc. v. Electronic Arts Inc*., 2010 WL 3463378 at *6 (S.D. Cal. Aug. 31, 2010) ("injunction would violate the public's interest in fair and healthy competition").

IV. CONCLUSION

For the reasons set forth above, Defendants respectfully request that the Court deny Plaintiffs' motion for a preliminary injunction.

Dated: January 31, 2013

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